REMARKS

Claims 1, 3, 5, 6, 8 and 9 are pending and stand rejected.

Claims 2 and 4 are withdrawn from consideration.

Claims 5, 8 and 9 are cancelled herein.

New Claims 18 – 21 are presented, and find support at original Claim 1. The status of New Claims 18 – 21 is "Withdrawn – New" in compliance with 37 C.F.R. §1.121(c) in light of OG Notice: 05 July 2005 ("Acceptance of Certain Non-Compliant Amendments Under 37 C.F.R. §1.121(c)"), as reflected at M.P.E.P. §714(II)(C)(E).

New Claims 22 – 23 are presented, and find support at original Claim 3.

New Claims 24 – 26 are presented, and find support at original Claim 6.

Original Claims 3, 6 and 9 were inadvertently provided with a status of "Previously Presented" in Applicants' response and Amendment dated May 29, 2007. The status of Claim 3 is amended herein to a status of "Original," Claim 9 is cancelled, and Claim 6 is indicated as "Currently amended" based on amendments presented herein.

Claim 1 is amended to recite an "antagonist antibody that specifically binds to DCRS5 (SEQ ID NO:2), or antigen binding fragment thereof." Support for the amendment is found, *e.g.*, at paragraphs [0035], [0083], [0104-0105] and [00138] of the specification as-filed, and at original Claim 5.

Claim 6 is amended to update the dependency and antecedent basis.

The specification is amended to correct a typographical error.

Applicants believe that no new matter is added by way of amendment.

I. Priority

Applicant notes with appreciation Examiner's acknowledgement of priority to 5/10/2000.

II. Rejection of Claims 1, 3, 5, 6, 8 and 9 under 35 U.S.C. §112, First Paragraph

The Examiner rejected Claims 1, 3, 5, 6, 8 and 9 under 35 U.S.C. §112, first paragraph, for lack of **enablement** with respect to nucleic acid antagonists of DCRS5.

Applicants respectfully disagree with the enablement rejection. The article cited by the Examiner in support of his argument, Opalinska & Gewirtz (2002) *Nat. Rev. Drug Disc.* 1:503, indicates that despite any potential shortcomings discussed in the article, antisense and "other nucleic acid therapies are undergoing clinical trials," and one antisense drug (sodium fomivirsen) was approved by the FDA in August 1998 and was in use in the clinic. *Id.* at p.503 (Abstract) and p.507 (Box 1). In light of such nucleic acid based molecules being in human clinical trials, and approved by the FDA, the Office should generally presume that a therapeutic product or process is reasonably predictive of having the asserted therapeutic utility. M.P.E.P. §2107.03(IV).

Nevertheless, solely in order to facilitate prosecution, Claim 1 (and thus all claims dependent therefrom) is amended to no longer recite nucleic acid antagonists of DCRS5, and dependent Claims 8 and 9 are cancelled. The Office Action indicates that the specification is enabling for a method of treating a human subject experiencing a physiological disorder comprising administering an effective amount [of an] antagonist antibody. Office Action dated 08/09/2007 at p.2 (paragraph 4a). Accordingly, Applicants respectfully request withdrawal of the rejection of Claims 1, 3, 5 and 6 (as amended) under 35 U.S.C. §112, first paragraph, for lack of enablement with respect to nucleic acid antagonists of DCRS5.

The Examiner further rejected Claims 1, 3, 5, 6, 8 and 9 under 35 U.S.C. §112, first paragraph, for lack of **written description** with respect to nucleic acid antagonists of DCRS5. As explained above with reference to the enablement rejection, Claims 8 and 9 are cancelled herein, and Claim 1 (and thus dependent Claims 3, 5 and 6) is amended to no longer recite nucleic acid antagonists of DCRS5.

In light of these amendments to the claims, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. §112, first paragraph, for lack of written description with respect to nucleic acid antagonists of DCRS5.

III. Rejection of Claims 1 and 5 under 35 U.S.C. §112, Second Paragraph

The Examiner rejected Claims 1 and 5 under 35 U.S.C. §112, second paragraph, because Claim 1 is allegedly vague and indefinite for reciting "a binding composition

derived from the antigen binding site of an antibody." Applicants disagree and believe that a binding composition derived from the antigen binding site of an antibody would be understood by one of skill in the art when read in light of the specification. Specifically, paragraph [0022] provides several examples of binding compositions derived from the antigen binding site of an antibody, including polyclonal, monoclonal and humanized antibodies, as well as Fab, Fv and F(ab')2 antibody fragments. Paragraph [0035] also lists diabodies, single chain antibodies, bifunctional antibodies and peptide mimetics of antibodies. Paragraph [0104] also discloses single chain versions of antibodies.

Nevertheless, solely in order to facilitate prosecution, Claim 1 is amended to recite "an antagonist antibody that specifically binds to DCRS5 (SEQ ID NO: 2), or antigen binding fragment thereof," obviating the rejection.

The Examiner also rejected Claim 1 under 35 U.S.C. §112, second paragraph, for reciting "an antagonist of DCRS5 (SEQ ID NO:2)." It is allegedly unclear whether "SEQ ID NO: 2" refers to DCRS5 or the antagonist thereof. Applicants disagree. It is abundantly clear in light of the specification that SEQ ID NO:2 refers to DCRS5, and not an antagonist thereof. *See, e.g.*, paragraphs [0029], [0033], [0055], [0063], [0069], [0083], original Claim 7(a), and SEQ ID NO:2 itself. More specifically, it is stated plainly at paragraph [0033] that "[a]s used herein, the term DCRS5 shall be used to describe a protein comprising the amino acid sequence of SEQ ID NO:2."

Nevertheless, Claim 1 is amended to recite "an antagonist antibody that specifically binds to DCRS5 (SEQ ID NO:2), or antigen binding fragment thereof," in which the fact that SEQ ID NO:2 refers to DCRS5 is even more clear than it was previously.

In light of the arguments present here, and the amendment to Claim 1, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. §112, second paragraph.

IV. New Claims 18 - 26

In the interest of compact prosecution, New Claims 18 – 26 are presented solely to present the individual elements of Claims 1, 3 and 6 as separate dependent

claims. New Claims 22 – 26 read on elected species. New Claims 18 – 21 are directed to non-elected species. Upon allowance of generic Claim 1, Applicants respectfully request allowance of all currently withdrawn claims.

Conclusion

Applicants' current response is believed to be a complete reply to all the outstanding issues of the latest Office Action. Further, the present response is a *bona fide* effort to place the application in condition for allowance or in better form for appeal. Accordingly, Applicants respectfully request reconsideration and passage of the amended claims to allowance at the earliest possible convenience.

Applicant believes that no additional fees are due with this communication. Should this not be the case, the Commissioner is hereby authorized to debit any charges or refund any overpayments to DNAX Deposit Account No. 04-1239.

If the Examiner believes that a telephonic conference would aid the prosecution of this case in any way, please call the undersigned.

Respectfully submitted,

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